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For the Health Care Professional

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This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1. Device trade name(s)

Solventum™ Inadine™ (PVP-I) Non-Adherent Dressing

1.2. Manufacturer's name and address

Solventum Germany GmbH
Edisonstrasse 6
59174 Kamen
Germany

1.3. Manufacturer's single registration number (SRN)

DE-MF-000038373

1.4. Basic UDI-DI

01979982761010000000035Q7

1.5. Medical device nomenclature description / text

M040412 (DRESSINGS, WITH ANTISEPTICS)

1.6. Class of device

Class III according to Rule 14 of Regulation (EU) 2017/745 Annex VIII

1.7. Year when the first certificate (CE) was issued covering the device

1996 (under Medical Device Directive, 93/42/EEC)

1.8. Authorised representative, if applicable; name and the SRN

Not applicable

1.9. Notified Body's name and single identification number

DQS Medizinprodukte GmbH, 0297

2. Intended use of the device

2.1. Intended purpose

Inadine™ dressing is indicated for the management of ulcerative wounds, minor burns and minor traumatic skin loss injuries. Inadine™ dressing is designed to protect and minimize adherence to the wound bed and provides an antiseptic effect against bacterial organisms. In heavily infected wounds, systemic antibiotics may be used in conjunction with Inadine™ dressing.

2.2. Indication(s) and target population(s)

2.2.1. Indications

Inadine™ dressing is indicated for the management of ulcerative wounds, minor burns and minor traumatic skin loss injuries. Inadine™ dressing is designed to protect and minimize adherence to the wound bed and provides an antiseptic effect against bacterial organisms. In heavily infected wounds, systemic antibiotics may be used in conjunction with Inadine™ dressing.

2.2.2. Target population(s)

For use by medical professionals or under the guidance of a medical professional. Patient target group are all patients with ulcerative wounds or minor burns and minor traumatic skin loss injuries, even if infected, unless the patient´s condition limits the use.

2.3. Contraindications and/or limitations

Inadine™ dressing should not be used:

- where there is a known iodine hypersensitivity (allergy)
- before and after the use of radio-iodine (until permanent healing)
- in patients with severe kidney disease
- in pregnant and breast-feeding women
- in cases of Duhring's herpetiform dermatitis (a specific, rare skin disease)
- in patients with any thyroid diseases as povidone iodine may be absorbed

3. Device description

3.1. Description of the device

Inadine™ is a topical wound dressing made of low adherent viscose fabric impregnated with an ointment containing polyethylene glycol (PEG), purified water and 10% povidone iodine (PVP-I). Iodine is a topical antimicrobial. The dressing is supplied sterile.

Catalog Number(s)	Size/Dimension/Contents
P01481	5 x 5 cm 1 dressing / pouch, 25 pouches / primary box, 10 primary boxes / shipper box
P01481EE	5 x 5 cm 1 dressing / pouch, 25 pouches / primary box, 10 primary boxes / shipper box, currently not manufactured or sold
P01491	9.5 x 9.5 cm

Catalog Number(s)	Size/Dimension/Contents
	1 dressing / pouch, 10 pouches / primary box, 10 primary boxes / shipper box
P01491EE	9.5 x 9.5 cm 1 dressing / pouch, 10 pouches / primary box, 10 primary boxes / shipper box, currently not manufactured or sold
P01512	9.5 x 9.5 cm 1 dressing / pouch, 25 pouches / primary box, 10 primary boxes / shipper box
P01512EE	9.5 x 9.5 cm 1 dressing / pouch, 25 pouches / primary box, 10 primary boxes / shipper box, currently not manufactured or sold

3.2. A reference to previous generation(s) or Variant (s) if such exist, and a description of the differences

Not applicable.

3.3. Description of any accessories which are intended to be used in combination with the device

There are no accessories associated with this product.

3.4. Description of any other devices and products which are intended to be used in combination with the device

When used, Inadine™ dressing should be covered and secured with a secondary dressing of choice.

4. Risks and warnings

4.1. Residual risks and undesirable effects

Risk analysis has confirmed that Inadine™ dressing is suitable for its intended use without any significant risk for patients or users and that the benefit of the product outweighs the potential risks associated with using the product. See Section 4.2 for a detailed listing of warnings and precautions.

4.2. Warnings and precautions

Inadine™ dressing must be used under medical supervision:

- in new-born babies and infants to the age of 6 months as povidone iodine may be absorbed through unbroken skin
- to treat deep ulcerative wounds, burns or large injuries.

Medical supervision should be sought if using Inadine™ dressing for more than one week.

Do not reuse. Reuse may result in infection or cross contamination.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

Not applicable.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

No other marketed devices are being claimed for equivalence.

5.2. Summary of clinical data from conducted investigations of the device before CE-marking, if applicable

Two (2) clinical trials were conducted on Inadine™ dressing, both reported on patients with venous ulcers that were treated with Inadine™ dressing. The follow-up time ranged from 3 weeks to 12 weeks. By the end of the studies, there was a reported decrease in mean ulcer size and improvement of the patient's condition measured by pain, granulation, exudate, odor, and edema.

5.3. Summary of clinical data from other sources (if applicable- if not applicable use N/A)

Clinical literature searches for Inadine™ dressing were conducted in 2 separate databases, covering the period of 01-JAN-2018 through 31-JAN-2025. The literature review identified 15 articles reporting on a total of 724 patients. These studies evaluated patients with conditions that included split thickness grafts, minor burn wounds, chronic wounds, venous leg ulcers, and diabetic foot ulcers.

The clinical literature provides evidence that Inadine™ dressings are well established devices and perform as intended. The data supporting the performance and safety profiles of the devices show compliance with the relevant safety and performance requirements as well as state of art.

5.4 Overall summary of the clinical performance and safety

Inadine™ is designed to protect and minimize adherence to the wound bed and provides an antiseptic effect against bacterial organisms. Safety and performance of Inadine™ is substantiated by clinical investigations, clinical data from literature, the evaluation of post-market experience data and nonclinical testing. Two (2) clinical studies in human subjects have been performed to assess the safety and/or performance of Inadine™ dressing. These studies demonstrated the suitability of the product for management of ulcerative wounds and prevention of infection in minor burns and minor traumatic skin loss injuries. Additionally, clinical data from the literature review, including 15 published articles and 724 patients, confirmed the suitability of Inadine™ dressing for its intended use. Evaluation of post-market surveillance data demonstrated that there are no safety or performance concerns with the use of Inadine™. Complaint rates were reported to be consistently low in the past years

and according to the reviewed complaint data, there's no indication that the use/ handling of the products causes dissatisfaction or concerns amongst the users. Inadine™ dressing underwent several tests to verify the safety of the medical devices. All data met acceptable criteria.

The product literature is consistent with the clinical data and technical documentation. The indications for use and claims for performance / efficacy and safety were found to be substantiated by sufficient evidence.

5.5 Ongoing or planned post-market clinical follow-up

A PMCF study is not planned for Inadine™ dressing. The product has a long history of suitable use, and innovation/novel aspects are not relevant. No significant changes to the product or its intended use have been completed. The product has a low to moderate risk level based on the design, invasiveness, patient target group, and clinical procedures. No questions have arisen regarding the severity of the disease/treatment challenges, and no questions have arisen regarding the generalizability of the clinical investigation results. No new risks have been identified for unstudied subpopulations. Validation is sufficient for this product's intended use and indications for use, and no discrepancies exist between the existing validation and for the expected life of the product. No additional risks have been identified in the literature or other data sources for similar marketed devices. No interactions with other medical products have suggested new unmitigated risks. Additional verification of safety/performance of the product with a larger clinical population is not warranted as the product has a long history of suitable use, and no additional unmitigated risks have been identified. No new information on safety/performance has been identified suggesting the need for a specific PMCF activity. The medium/long-term safety and clinical performance is already known from previous use of the device.

Device specific data will be continuously collected through the post-market surveillance process. Post-market surveillance will evaluate reported adverse events, literature, and clinical data with the aim of confirming the safety and performance throughout the expected lifetime of the device, and to ensure the continued acceptability of identified risks and of detecting emerging risks based on factual evidence.

6. Possible diagnostic or therapeutic alternatives

For treating chronic wounds like ulcerative wounds or traumatic wounds like minor burns clinicians have a variety of wound dressing to choose from.

For ulcerative wounds, the choice of dressing is largely determined by the causes of the ulcer, wound location, depth, amount of scar or slough, exudates, condition of wound margins, presence of infection and pain, need for adhesiveness, and conformability of the dressing. Advanced wound care dressings for ulcerative wounds include hydrocolloids, hydrogels, foams, films, alginates, and silver-impregnated dressings. Dressings containing antimicrobial

substances like iodine and silver may aid in controlling bacterial burden and managing wound infection.
For minor burns or minor traumatic skin loss injuries, often dressings are used which maintain a moist wound environment to optimize healing or dressings with antimicrobial substances to control the bioburden. Therapeutic alternatives to Inadine™ dressing would be hydrogels, hydrocolloids or silver-impregnated wound dressings.

7. Suggested profile and training for users

For use by medical professionals or under the guidance of a medical professional.
Users should always follow the directions for use as detailed in the Instructions for Use.

8. Reference to any harmonized standards and Common Specifications applied

Inadine™ dressing is compliant with all applicable harmonized standards. The product conforms with the relevant safety and performance requirements set out in Annex I of EU Medical Device Regulation (MDR) (EU) 2017/745 and is in accordance with MDR Article 61, Annex XIV and MEDDEV 2.7/1 Rev 4. Inadine™ dressing is in compliance with the standards illustrated in the table below:

Standard	Description
EN 556-1	Sterilisation of medical devices – Requirements for medical devices to be designated 'sterile' – Part 1: Requirements for terminally sterilised medical devices
EN ISO 10993-1	Biological Evaluation of Medical Devices – Part 1: Evaluations and Testing
EN ISO 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity
EN ISO 10993-4	Biological evaluation of medical devices - Selection of tests for interaction with blood
EN ISO 10993-5	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
EN ISO10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
EN ISO10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Standard	Description
EN ISO10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
EN ISO10993-18	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23	Biological evaluation of medical devices – Part 23: Tests for irritation
EN ISO 11137-1	Sterilisation of Health Care Products – Radiation – Part 1: Requirements for the development, validation and routine control of a sterilisation process for medical devices.
EN ISO 11137-2	Sterilisation of Health Care Products – Radiation – Part 2: Establishing the sterilisation dose
EN ISO 11607-1	Packaging for Terminally Sterilised Medical Devices – Part 1: Requirements for Materials, sterile barrier systems, and packaging systems
EN ISO 11607-2	Packaging for Terminally Sterilised Medical Devices – Part 2: Validation Requirements for forming, sealing and assembly processes.
EN ISO 11737-1	Sterilisation of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2	Sterilisation of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process
EN ISO 14644-1	Cleanrooms and associated controlled environments – Part 1 Classification of air cleanliness
EN ISO 14644-2	Cleanrooms and associated controlled environments – Part 2 Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1	Medical Devices – Symbols to be used with Medical Device Labels, Labeling, and Information Supplied – Part 1: General Requirements
EN ISO 20417	Medical devices. Information to be supplied by the manufacturer
EN ISO 22442-1	Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management
EN 62366-1	Medical Devices – Part 1 Application of usability engineering to medical devices

9. Revision history

SSCP Version Number	Date issued	Change description	Revision validated by the Notified Body
1	2024-08-14	Initial document under Solventum Brand –this document is created based on SSCP-05-761128 owned by 3M Deutschland GmbH	☐Yes Validation language: English ☒No

2	2024-08-27	Clarification of contraindication "Inadine dressing should not be used if you are being treated for kidney problems" to be medically more specific to "Inadine dressing should not be used if you are being treated for severe kidney disease"	☐Yes Validation language: English ☒No
3	2025-04-07	Rephrasing of contraindication "Inadine dressing should not be used if you are being treated for severe kidney disease" to "Inadine dressing should not be used in patients with severe kidney disease" based on authority feedback	☐Yes Validation language: English ☒No
4		Update of clinical literature search period	☐Yes Validation language: English ☐No